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10/729,415	12/05/2003	Paul Kudma	3873 P 039	8381

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

DATE MAILED: 03/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/729,415	KUDRNA ET AL.	
	Examiner	Art Unit	
	Diane Yabut	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>05/17/04; 02/02/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) received on 17 May 2004 is acknowledged. In addition, the IDS received on 02 February 2006 is also acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statements.

Specification

2. The disclosure is objected to because of the following informalities:

Page 2: line 5 reads "a particular users desires" and should read --a particular user's desires--.

Page 6: line 6 reads "tangs 72" and should read --tangs 77--.

line 7 reads "They 79 also" and should read --They also--.

Page 7: line 16 reads "a two downwardly" and should read --two downwardly--.

Page 8: line 22 reads "to it 'piercing position'" and should read --to a 'piercing position'--.

Page 9: line 26 reads "the external threats 166 mate" and should read --the external threads 166 mate--.

Page 10: line 5 reads "the dial adjuster 180" and should read --the dial adjuster 160--.

line 6 reads "the adjuster 180" and should read --the follower 180--.

Page 16: line 16 reads "60 is can be" and should read --60 can be-- or --60 is--.

line 29 reads "has occurring" and should read --has occurred--.

Page 17: line 7 reads "withdrawing" and should read --withdrawn--.

Appropriate correction is required.

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3. The abstract of the disclosure is objected to because of the following:

(1) It is more than one paragraph

(2) It exceeds 150 words

(3) In line 8, "in communications" should read --in communication--.

(4) In line 10, "the magnetic forces from the magnetic affect the member, and releasing the one of" should read --the magnetic forces from the magnet affect the member, and releasing one of--.

Correction is required. See MPEP § 608.01(b).

Claim Objections

4. Claims 19 and 20 are objected to because of the following informalities:

Claim 19: In line 4, "a lancet" should be --the lancet--.

Claim 20: In line 8, "connect" should be --connected--.

5. Claim 29 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim (Claim 6). Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 29 is dependent upon 25, which is dependent upon Claim 6 wherein the same limitation is described in lines 6-8 about the lancet, as it is in lines 17-19 of Claim 29.

6. **Note:** Claim 8 recites "the moving means, the holding means, and the activator means," (line 21), and is dependent on Claim 6, which recites "a mechanical or electrical force" (line 5), "a lever member" (line 8), and an "activator" (line 10), which are the respective apparatuses. Claim 8 does not invoke 35 U.S.C. § 112, 6th paragraph, as it is

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not in the proper form. However Claim 8 is independent on Claim 6, and should then properly refer to the respective apparatuses rather than the "means."

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 9-11,14-19,20-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. The limitation "the housing" is recited in the following claims:

Claim 9 in lines 23 and 24; Claim 10 in line 28; Claim 11 in line 30; Claim 15 in line 12; Claim 16 in line 21; Claim 17 in lines 24 and 30; Claim 20 in line 8. Claim 24 in line 26.

There is insufficient antecedent basis for all the above limitations in the claims. Claims 9-10,15-17,20, and 24 are dependent upon Claim 6 (Claim 24 being dependent upon 23, which is in turn dependent upon Claim 6), which does not mention "a housing."

10. The limitation "the collar" is recited in the following claims:

Claim 14 in lines 8 and 9; Claim 15 in lines 12 and 13; Claim 16 in line 21; Claim 17 in lines 24, 25, 27, and 29; Claim 18 in line 2, and therefore Claim 19 (dependent on Claim 18); Claim 21 in lines 12 and 13; Claim 22 in lines 17 and 19; Claim 23 in line 23. There is insufficient antecedent basis for all the above limitations in the claims. Claims 14-18 and 21-23 are dependent upon Claim 6, which does not mention "a collar," but rather "a member," and therefore "the collar" should be changed to --the member--.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 1,3,10, and 17 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 2,7,10, of copending Application Pub. No. **20050125019**. Although the conflicting claims are not identical, they are not patentably distinct from each other because they encompass the same invention. In other words, the independent Claim 1, and the dependent Claims 3,10, and 17 (all of which encompass Claim 6) of the application under examination are rejectable as being an obvious modification over the claims of the copending application.

13. Claim 1 recites "a magnetic element" (see line 4), "a member capable of being affected by magnetic forces emanating from the magnetic element" (see lines 5-6), and "a lancet movable between a withdrawn position and a piercing position"

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(see lines 7-10). It is clear that all the elements of Claim 1 are to be found in Claim 2 (as it is dependent upon Claim 1) of the copending application.

14. Claim 3 recites the magnetic element's magnetic forces "affect the member by either attracting and pulling the member towards the magnetic element or repulsing and pushing the member away from the magnetic element" (see lines 16-18). It is evident that all the elements of Claim 3 are to be found in Claim 7 (as it encompasses Claim 6) of the copending application.

15. Claim 10 recites "an adjuster adapted to selectively control the positioning of the piercing position relative to the housing" (see lines 27-28). It is clear that all the elements in Claim 10 are to be found in Claim 10 (as it encompasses Claim 8) of the copending application.

16. Claim 17 recites "the magnetic element and the collar" are within "the housing" and "the magnetic forces of the magnetic element attract the collar to the magnetic element" in the armed position (see lines 24-26). Also recited is that when the activator releases the collar, "the collar travels toward the magnet" and "past the magnetic element due to the momentum of the traveling collar" and back to a "position within the housing" (see lines 27-30). It is evident that all the elements in Claim 17 are to be found in Claim 15 (as it encompasses Claim 8) of the copending application.

17. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

19. Claims 1-3,5,8-11,26-28,30,31,33,34 are rejected under 35 U.S.C. 102(b) as being anticipated by **Kheiri**, US Patent No. **6,364,889**. **Kheiri** discloses an electronic lancing device that uses magnetic forces. **Figure 2** is a good representation of the device.

Claim 1: **Kheiri** discloses a magnet **50**, a bobbin **35** (“member”) and a lancet **30** (col. 4, lines 19-20), wherein the bobbin is movable from a “retracted” (“withdrawn”) position to an “activated” (“piercing”) position along with a removably attached lancet **30** (col. 4, lines 44-55).

Claims 2-3: **Kheiri** discloses a bobbin **35** with a second tubular body member **515** that is wrapped by a coil of wire **520** (col.5, lines 50-51), which is controlled by an electronic circuit (col 1, lines 60-62). The electric circuit **40** is able to direct current through parts of the coil of wire **520** on bobbin **35**, such that the bobbin **35** is capable of being both attracted to or repulsed by the magnet **50** (col. 7, lines 14-18 and 39-42). The electric current **40** can be considered the “arming element” in that it moves the lancet from the piercing position to a retracted, or “armed” position, so that it is ready for piercing.

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Claim 5: Kheiri discloses a firing button **22** that is connected to at least one wire leading to the electronic circuit **40** that controls the movement of the bobbin **35**, and therefore the lancet **30**, from a retracted position to a piercing position (col. 4, lines 57-59).

Claim 8: Kheiri discloses a housing **10** that provides an encasing for the lancing device **5**, which includes the lancet **30**, magnet **50** and bobbin **35** (col. 4, lines 21-25).

Claim 9-11: The lancet **30** is in the retracted position when it is fully within the end cap **25**, and in the activated position when it has advanced from the end cap **25** – the end cap **25** can be considered part of the “housing” here. Kheiri discloses a removable end cap **25**, which allows for removal and insertion of a lancet **30** in preparation for use (col. 3, line 67 and col. 4, lines 1, 13-14). The end cap **25** also allows control for the depth of puncture, or is an “adjuster” (col. 3, line 58).

Claim 26: See explanations for Claims 1 and 3.

Claims 27-28: Kheiri discloses a magnet **50** that has a generally cylindrical body member **405** (see col. 5, line 33). Also, bobbin **35** has a generally tubular body member **511** (see col.5, lines 66-67). The bobbin **35** is disposed over the magnet **50** (see col. 1, lines 59-60), which would suggest that the inner diameter of the bobbin is capable of accommodating the diameter of the magnet so as to permit the bobbin to be disposed over the magnet.

Claim 30: See explanation for Claim 1. “Steady state” is best understood as when the member is disposed over the magnet, and not necessarily distinguishable from the “withdrawn” position.

Claim 31: See explanation for Claim 6 below (paragraph 21).

Claim 33: Kheiri discloses a steel block **52** that is coaxially centered and mounted on top of the cylindrical magnet **50**, and the steel block **52** brings the majority of the magnetic flux lines to intersect the coils disposed around the bobbin **35** (col. 6, lines 43-46).

Claim 34: See explanation for Claim 27.

Claim Rejections - 35 USC § 103

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

21. Claims 4,6,7,12-14,16-17,20-22,23,29, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Kheiri** (US Patent No. **6,364,889**) in view of **LeVaughn**, US Patent No. **6197040**.

Claim 4: Kheiri disclosed all claimed structure of the lancet device (see explanations for Claims 1,2-3,5, paragraph 19), except for the lever member. LeVaughn teaches a lancing device with a releasable connector **28** ("lever"), or cantilever latch, which has a cantilever arm for releasable contact with lancet holder **20**, and has teeth **50** that engage with teeth **52** on the holder (Figures 2 and 7-7A, col. 4, lines 42-44). This is achieved by a slider **26** that pushes the lancet holder **20** in a cocked position, as well as a forward position, as it pushes down on the releasable connector **28** forcing the engagements between the teeth **50** and **52** together, preventing movement (col. 4, lines 15-20). The releasable connector **28** prevents the lancet holder **20** and slider **26** from

moving unintentionally, and allows for the cocking and ejecting mechanisms not to be directly linked (col. 2, lines 8-10, 24-26). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a lever member, as taught by LeVaughn, on the lancing device of Kheiri for holding the bobbin **35** in order to mechanically separate the retracted and piercing positions to avoid unintentional piercing of the lancet.

Claim 6: Kheiri disclosed all claimed structure of the lancet device (see explanations for Claims 1-3,5), except for the lever member, which is explained above in Claim 4.

Note: Kheiri discloses all claimed structure for Claims 7,12-14,20,23, and 29 which are all dependent on Claim 6, but are rejected under 35 U.S.C. 103(a) based on the lack of the lever member in Claim 6 (see explanation for Claim 4), and therefore provide disclosures for only the additional claimed structures as anticipated by Kheiri.

Claim 7: See explanation for Claim 3 (paragraph 19).

Claim 12: See explanation for Claim 11 (paragraph 19).

Claim 13: See explanation for Claim 27 (paragraph 19).

Claim 14: Kheiri discloses a lancet **30** that is removably attached to a bobbin, or "member" (col.3, lines 52-53).

Claim 20: See explanation for Claim 11 (paragraph 19).

Claims 21-22,32: See explanation for Claim 4. The releasable connector **28** ("lever"), or cantilever latch, is similar to the button switch **150** disclosed by the applicant, in that its teeth **50** engages with the teeth **52** on the lancet holder **20** in order to prevent movement in the armed position. It is also similar to the activator means in that is

capable of releasing the engagement between the teeth. The teeth **52** on the lancet holder **20** of LeVaughn are in a planar orientation, however it would be obvious to one skilled in the art at the time of invention to modify the teeth of in a circumferential manner on the bobbin **35** of Kheiri when combining the releasable connector **28** with the lancet device of Kheiri in order to properly hold the cylindrical bobbin **35** in the armed position.

Claim 23: See explanation for Claim 27 (paragraph 19). "Steady state" is best understood as when the member is disposed over the magnet.

Claim 29: Kheiri discloses a bobbin **35** with a second tubular body member **515** that is wrapped by a coil of wire **520** (col.5, lines 50-51), which is controlled by an electronic circuit (col.1, lines 60-62). When current flows through the wire **520**, the bobbin **35** and lancet **30** extend towards the puncture site ("piercing position"), and upon retraction, they both return to the retracted ("withdrawn") position.

22. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over **Kheiri** (US Patent No. **6,364,889**) in further view of **Simons et al.**, US Patent No. **5871494**.

Claim 25: Kheiri disclosed all claimed structure of the lancet device (see explanations for Claims 1,2-3,5, paragraph 19), except for the dial adjuster and follower for controlling the piercing position. Simons et al. teaches a depth adjuster **560**("dial adjuster") that is threaded with a cocking tube **562** ("follower") (col.11, lines 64-66), and is rotated causing the cocking tube **562** to move to a position that determines the location of flange **572**, or a limiting stop, which in turn determines how far the lancet **216** can extend forward (col.12, lines 65-75 and col.13, lines 1-9). This design allows a user to

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control the depth of penetration for optimal blood sampling and pain level (col.13, lines 15-17). It would have been obvious to one of ordinary skill in the art at the time of the invention to provide a depth adjuster and cocking tube, as taught by Simons et al., to the device of Kheiri, as well as the lever member of LeVaughn, in order to benefit from user control for improving blood sampling and lowering pain level.

Allowable Subject Matter

23. Claims 15-19, and 24 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claims 15-17: The collar, or "member," is interpreted to travel towards the magnetic element after the activator releases the member, meaning that the member is away from the magnetic element in the armed, or withdrawn, position, and therefore is separate from the steady-state position wherein the magnetic element holds the member within it or is disposed around it.

Claims 18-19: The outer shaft moving relative to the inner shaft is interpreted as meaning that the inner shaft does not move, but the other shaft does move. Also, the lancet is capable of being connected to and removed from the outer shaft.

Claim 24: The internal spring is interpreted as a connection between the arming member and the housing.

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. **Boecker**, Pub. No. US 2004/0098009 (disclosing an apparatus

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for body fluid sampling and analyte sensing; Figure 98 is especially pertinent), **O'Brien**, US Patent No. **4,924,879** (disclosing a blood lancet device), **Harding**, US Patent No. **5,613,978** (disclosing an adjustable tip for lancet device), **Verdonk**, U.S. Patent No. **6,306,152** (disclosing a lancet device with skin movement control and ballistic preload), **Hamamoto**, U.S. Patent No. **6,730,046** (disclosing a body fluid sampling device).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


EUGENE KIM
SUPERVISORY PATENT EXAMINER

DDY